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TITLE: The Effects of Low to Moderate Intensity Exercise on Fatigue in Breast Cancer Patients Following Clinical Treatment

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| 14. ABSTRACT<br><br><b>Purpose:</b> of this study was to test the effect of low to moderate intensity exercise on fatigue and physical functioning in women who have completed treatment for breast cancer. <b>Sample:</b> Twenty-two women, ages 43-79, who had completed treatment for breast cancer, were randomly assigned to an exercise (n= 12) or control group (n = 10). The exercise group participated in a low-moderate intensity (30-50% heart rate reserve) aerobic exercise program 3 times a week for ten weeks. The control group did not participate in the exercise program. Physical functioning was measured by assessing peak aerobic capacity with a treadmill protocol. Both groups recorded their weekly level of fatigue using a Linear Analogue Self-Assessment Scale (LASA) and the Schwartz Cancer Fatigue Scale (SCFS). <b>Results:</b> Peak aerobic capacity increased significantly (25%, p = .005) in the exercise group. The control group showed a decrease of 5.2%. Fatigue reported with the Schwartz scale decreased in the exercise group and increased in the control group. This change was statistically significant between the groups (p = .0003) and within the groups (p = .01). Fatigue reported with the LASA scale decreased in the exercise group and increased in the control group but the differences were not statistically significant between (p = .17) or within (p = .10) the groups. <b>Discussion:</b> This aerobic exercise program was effective in improving peak aerobic capacity and reducing fatigue (SCFS) in this group of breast cancer survivors. Guidelines for an exercise intervention are already in place for chronic diseases (diabetes, heart disease), but no guidelines are in place for cancer patients and survivors. Lower intensity aerobic exercise should be considered for this population. Low to moderate intensity exercise is a safe, beneficial, efficient, and cost-effective tool for improving fatigue in breast cancer survivors. |             |                                  |                            |   |   |
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## **I. INTRODUCTION**

Fatigue is the most common symptom resulting from cancer and the treatments following diagnosis. Published reports suggest that more than 70% of patients receiving chemotherapy or radiation reported fatigue symptoms (Courneya et al. 2000). These symptoms included such things as tired legs, whole body tiredness, and feelings of wanting to lie down (Mock et al. 2001). Additionally, fatigue increases with the number of radiation or chemotherapy cycles (Mock et al. 1997). Several studies have investigated the effect of exercise on fatigue in cancer patients (Dimeo, F.C., et al., 1997, Mock, V., et al. 1997, Schwartz, A.L., et al. 2001).

Data is being collected that suggests exercise can reduce fatigue in people surviving cancer. Little data however exists as to the appropriate intensity of exercise to reduce fatigue. Burnham et al. (2001) found that low intensity exercise was equally as effective as moderate intensity exercise in reducing fatigue in exercising cancer survivors. If this result holds true, it may be that lower levels of exercise intensity may be as effective and better tolerated by patients who are suffering from extreme fatigue.

The purpose of this study is to investigate the effects of low to moderate intensity exercise on fatigue and physical function in cancer survivors.

## **II. BODY OF RESEARCH**

### **A. Description of Research Project**

#### **Specific Aims**

The specific aims of this study are to test the effect of low to moderate intensity aerobic exercise treatment on self-reported fatigue and physical functioning for women who have completed therapy for breast cancer.

#### **Sample**

To be included in this study women must be: a) 20-80 years of age, b) have stage I or II breast cancer for which treatment concluded one to twelve months prior to enrolling in this study, and c) have been cleared to participate by their primary care provider. Women will be excluded if they have are being treated for other chronic diseases which would contribute to their fatigue such as congestive heart failure.

#### **Tools**

A modified Linear Analogue Self-Assessment Scale (LASA) and the Schwartz Cancer Fatigue Scale (SCFS) are used to measure self-reported fatigue levels. The LASA anchors, on a 100 mm line, for fatigue are “not at all fatigued” and “extremely fatigued;” for energy levels they are “not at all energetic” and “extremely energetic.” The score is determined by measuring the placement of the mark on the line. Scores range from 0 to 100. Test-retest reliability of the scale was tested 12 weeks apart in 60 cancer patients (Sutherland, 1989). Test-retest of the LASA averaged  $r = .79$ , which the researchers concluded, was a feasible, reliable and valid measure of emotional distress for cancer patients. The SCFS asks participants to rate: tired, difficulty thinking, overcome, worn out, and listless from 1 being “not at all,” 2 a little, 3 moderately, 4 quite a bit and 5 extremely. The SCFS demonstrated strong internal consistency reliability exceeding Cronbach alpha  $> .85$  (Schwartz, 2002).

Physical functioning is determined by measuring aerobic capacity during treadmill testing. The aerobic exercise will be preformed on treadmills, stationary bicycles, and stair climbing machines. The subjects will be started at 25-35% of their heart rate reserve increasing to 40-60% by week 10. Demographic, cancer, and exercise characteristics are determined by asking participants to fill out a detailed form. Questions include their age, address, list of allergies, medications, previous medical history, level of education, and ethnic affiliation. Cancer characteristics include a short history of the onset of cancer, assessment, and treatment. Exercise characteristics include current and past exercise programs, frequency of exercise and duration, types of work and physical activities.

## **Design and Procedures**

Subjects have been recruited from local medical centers, clinics, and hospitals in both Central and North Central Washington State. Recruitment is done through advertising with flyers, posters, letters, and word of mouth. Initial screening is conducted by phone interview. Each subject is informed both verbally and in writing as to the purpose and admission criteria of this study. Subjects who meet admission criteria sign and received a copy of the informed consent. The subjects were then randomly assigned to an exercise or control group at the time demographics and baseline measures are obtained. The exercise group reports for a controlled exercise program 3 times a week for 10 weeks. All subjects have aerobic capacity measured at the beginning and end of 10 weeks. Fatigue is measured weekly for 10 weeks.

### **Exercise Intervention**

All participants spend the first 3-5 minutes doing aerobic warm-up exercises. They then spend 5 minutes stretching. The following 14 minutes consists aerobic exercise on treadmills, stationary bicycles, stair-climbing machines, and aerobic dance. This is followed by an aerobic cool-down (3-5 minutes) and stretching (5-8 minutes) for a total of 30-37 minutes per session.

The aerobic exercise period, in accordance to the ACSM's recommendation (American College of Sports Medicine Position Stand, 1998), is increased by 2 minutes per week to total 32 minutes by week 10. The subjects exercise 30-37 minutes initially and increase to 50-59 minutes duration by the end of 10 weeks. Detailed instruction of the exercise program and equipment used is provided to each participant. Results of the study, when available, will also be provided to each of the participants at the conclusion for those who are interested.

Heart rate is monitored using a Polar heart rate monitor (Target model). Aerobic capacity testing will be conducted on a treadmill. Subjects will establish a comfortable walking pace of 1.5 to 4 mph. The grade of the treadmill is increased 1% each minute and continues till the subjects report volitional exhaustion. Heart rate is monitored during treadmill testing with an electrocardiogram. Oxygen consumption is being measured using an open circuit indirect calorimetry technique. The metabolic cart is calibrated to known concentrations of oxygen and carbon dioxide prior to each test. The subjects breath into a 2-way valve system during the test, which is connected to the metabolic cart. The subjects inhale room air while their exhaled gases go directly into the metabolic cart. This process permits quantification of expiratory volumes, O<sub>2</sub> concentrations, and carbon dioxide concentrations.

### **Data Analysis**

Demographic data was measured by descriptive statistics (measures of central tendency and dispersion). Aerobic capacity data is being analyzed with a paired t-test. A repeated measures ANOVA is used to determine if the changes to the self-reported fatigue levels

are statistically significant. All values are reported as means and standard errors. An alpha level of  $<0.05$  is considered statistically significant.

## **B. EXPERIMENTAL LEARNING**

### **Recruitment of Subjects for the project**

- Assisted with posters development and placed in appropriate sites for subject recruitment.
- Assisted with newspaper advertisements that have been placed in local newspapers for subject recruitment.
- Radio advertisements were developed and played on local radio stations for subject recruitment.
- The principal and co-investigator have contacted local medical groups and hospitals to recruit subjects.
- The principal and co-investigator contacted local support groups for subject recruitment.

### **Initial Data Collection Period and Randomization into Groups**

- Subjects are contacted and scheduled for the initial data collection test at the Central Washington University Exercise Science Laboratory.
- Subjects read and sign the informed consent document.
- Demographic and medical information is collected.
- Maximal aerobic capacity tests are conducted on the treadmill at the Exercise Science Laboratory.
- The fatigue scales are explained to the subjects and the initial fatigue measures are collected.
- Subjects are randomly assigned to either the exercise or control groups.
- Subjects are contacted and informed of their group status.

### **Ten-Week Training Program**

- The subjects in the exercise group perform supervised aerobic exercise three times a week for the ten-week study period.
- The initial exercise duration is 14 minutes of aerobic exercise. Exercise duration increases two minutes a week throughout the study. Exercise duration is recorded for each subject by the principle investigator.
- The initial exercise intensity is 25-35% of heart rate reserve. Intensity increases to approximately 40-60% of heart rate reserve by week ten. The principal and co-investigator calculate exercise intensity increases for each subject. Exercise intensity is measured during exercise with a Polar heart rate monitor.
- The control group performs their normal activities during this period with the exception of performing any new exercise programs.
- A modified Linear Analogue Self-Assessment Scale (LASA) and the Schwartz Cancer Fatigue Scale (SCFS) is used to measure self-reported fatigue levels. These

scales are given to all participants (exercise and control groups) weekly. The subjects return the scales to the principal investigator in stamped self-addressed envelope.

- The principal and co-investigator score and record all fatigue scales weekly.

### **Data Collection Period**

- Subjects are contacted after the conclusion of 10 weeks time period and scheduled for the final data collection test at the Central Washington University Exercise Science Laboratory.
- Maximal aerobic capacity tests are conducted on the treadmill at the Exercise Science Laboratory.
- The two fatigue scales are administered for the final time.

### **Statistical Analysis and Report Writing**

- Final statistical analyses will be performed on the fatigue and maximal aerobic capacity data.
- Findings will be summarized into a final report.
- An initial manuscript will be prepared for publication.

### **Summary (trainee's) Role in the Research Project**

- Scientific design of the project
- Recruitment of subjects
- Initial data collection including medical and demographic information, maximal aerobic capacity testing, and fatigue measures.
- Randomization of subjects into exercise control group
- To supervise the ten-week training period.
- To collect weekly fatigue data.
- Conduct the final data collection period.
- Perform statistical analysis.
- Summarize findings into final report for Master's thesis
- Preparing initial manuscript for publication.

### **Value**

- The training has been very valuable, and has actually changed my life. I have an incredible passion for research for improving cancer survivor's quality of life. I've enhanced my skills in the use of exercise as a rehabilitative tool for the reduction of fatigue in breast cancer survivors. This is important as few medical professionals are trained in this field. I've been able to apply these new research skills to establish additional exercise programs for breast cancer survivors and to continue to explore this much-needed area of research.



### **C. DIDACTIC LEARNING (on going till December 2005, months 21-24)**

Completed Courses to Date (months 18-20) - Cumulative GPA 3.8

- Research Methods (5 credits) – Nursing Methods
- Health Promotion (3 credits) - Nursing
- Pain Management (3 credits) – Nursing
- Biological Aspects of Cancer: Implications for Care (3 credits) – Nursing
- Pharmacotherapeutics for Acute/Critical Illness (3 credits) – Pharmacology
- Loss, Grief, Death, and Dying in Clinical Practice (4 credits) - Nursing
- Seminar in Cardiovascular Nursing (3 credits) – Nursing
- Physiology and Biology (4 credits) – Department of Physiology
- Cancer Pharmacotherapeutics (2 credits) – Pharmacology
- Symptom Management in Cancer Care and Serious Illness (3 credits) – Nursing
- Human Responses II, Cellular and Molecular Immunology (3 credits) – Nursing
- Human Responses I, Advanced Health Assessment (3 credits) – Nursing
- Professional Issues (credits 2)- Nursing
- Prevention Therapeutics (3 credits) – Nursing
- Healthcare for Cancer Survivors: Medical, Gender, Spiritual (2 credits) Nursing
- Psychological Aspects of Rehabilitation (2 credits) – Rehab (complete months 21-24)
- Masters Thesis – on going, working on manuscript for publishing (extension filed)

### **D. Established Exercise Program in Rural North Central Washington**

- Researched exercise programs offered specifically for breast cancer patients and learned about the *Lebed Method: Focus on Healing through Movement and Dance*. The Lebed Method is a therapeutic exercise program for women who have had breast surgery, node dissection, radiation, chemotherapy, or suffer from chronic fatigue. The program was created to help breast cancer survivors live a better quality of life.
- Enrolled exercise rehabilitation interns from Central Washington University in training programs offered in Seattle Washington to learn the *Lebed Method*.
- Continued networking with medical centers in Central and North Central Washington (Yakima, Wenatchee, and Omak) to secure site for exercise classes to take place.
- Continued partnership with *The Wellness Place*, a cancer resource center located in Wenatchee, Washington, to assist with sponsoring the programs. Facilitated training for some of their personnel to teach the classes.
- Started initial 10-week exercise programs in September 2003. These exercise programs are now well established and ongoing in North Central Washington.

### III. KEY RESEARCH ACCOMPLISHMENTS

#### Key Findings

- A repeated measures ANOVA showed peak aerobic capacity increased significantly between (31.5%,  $p = .005$ ) and within ( $p = .0012$ ) the exercise group ( $16.5 \pm 8.0$  SD to  $21.7 \pm 9.4$  SD) over time. The control group showed a decrease in aerobic capacity of 5.4% ( $16.6 \pm 5.1$  SD to  $15.7 \pm 3.7$  SD).
- Body fat% decreased significantly (4.7%,  $p = .0001$ ) in the exercise group ( $29.7 \pm 3.7$  SD to  $28.3 \pm 3.8$  SD).
- Sit and reach increased significantly (9.7%,  $p = .004$ ) in the exercise group ( $30.9 \pm 7.2$  SD to  $33.9 \pm 4.8$  SD).
- BMI decreased and neared significance in the exercise group and increased in the control group.
- Fatigue reported with the SCFS decreased in the exercise group ( $17 \pm 1.7$  SE to  $8.08 \pm .96$  SE) and increased in the control group ( $11.8 \pm 1.5$  SE to  $15.5 \pm 2.6$  SE). This change was statistically significant between the groups ( $p = .0003$ ) and within the groups ( $p = .01$ ).
- Fatigue reported with the LASA scale decreased in the exercise group and increased in the control group but the differences were not statistically significant between ( $p = .17$ ) or within ( $p = .10$ ) the groups.
- Depression decreased significantly between (89%,  $p = .005$ ) and neared significance within ( $p = .0517$ ) the exercise group ( $23.0 \pm 18.9$  SD to  $2.5 \pm 4.0$ ) while depression increased in the control group ( $7.6 \pm 8.0$  SD to  $13.2 \pm 19.5$  SD).
- Anxiety decreased significantly between (86%,  $p = .03$ ) and within ( $p = .01$ ) in the exercise group ( $31.5 \pm 26.2$  SD to  $4.2 \pm 5.6$  SD).
- Confusion decreased significantly (70%,  $p = .04$ ) in the exercise group ( $21.0 \pm 17.9$  SD to  $6.3 \pm 14.1$ ) and increased in the control group ( $6.7 \pm 6.5$  SD to  $10.7 \pm 19.7$ ).
- Anger decreased significantly (72%,  $p = .02$ ) in the exercise group ( $14.3 \pm 21.4$  SD to  $4.0 \pm 8.8$  SD) and increased in the control group ( $4.6 \pm 4.6$  SD to  $13.8 \pm 23.3$  SD).
- There was no statistical difference between the groups on the measure of energy ( $p = .19$ ).

#### **IV. REPORTABLE OUTCOMES**

##### **Publications (Published Abstracts as of August 2005)**

- Burnham T., Nethery V., Frank J., Kemble K., (2005). *Relationship between fatigue and measures of emotional distress in exercising cancer survivors*. Medicine and Science in Sports and Exercise. 37:5, 2005.
- Frank, J., Burnham T., Kemble K., (2005). *Low-moderate intensity aerobic exercise improves quality of life indices and emotional distress in cancer survivors*. Medicine and Science in Sports and Exercise. 37:5, 2005.
- Sims C., Burnham T., D'Acquisto L., Papadopoulos C., Kemble K., (2005). *Low intensity aerobic exercise improves quality of life and body composition in breast cancer survivors*. Medicine and Science in Sports and Exercise. 37:5, 2005.

##### **Presentations**

- Presenter for poster and platform presentation titled *The Effects of Low to Moderate Intensity Aerobic Exercise on Fatigue in Breast Cancer Patients Following Clinical Treatment* at The Era of Hope, DOD Breast Cancer Research Program, Philadelphia, PA. June 8-11, 2005.
- Co-presenter with T. Burnham on paper titled *Relationship Between Fatigue and Measures of Emotional Distress in Exercising Cancer Survivors* at the annual meeting of the American College of Sports Medicine in Nashville, TN. June 1-4, 2005.
- Co-presenter with J. Frank on paper titled *Low-Moderate Intensity Aerobic Exercise Improves Quality of Life Indices and Emotional Distress in Cancer Survivors* at the annual meeting of the American College of Sports Medicine in Nashville, June 1-4, 2005.
- Co-presenter with C. Sims on paper titled *Low Intensity Aerobic Exercise Improves Quality of Life and Body Composition in Breast Cancer Survivors* at the annual meeting of the American College of Sports Medicine in Nashville, TN. June 1-4, 2005.

##### **Honors**

- 2004 Honorary Alumni, Wenatchee Valley College, Wenatchee, WA.
- 2005 Sigma Theta Tau International, Honor Society of Nursing.

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**TABLE 1. Subject Characteristics (mean  $\pm$  SD)**

| <i>n</i> = 22      | Control ( <i>n</i> = 10) | Exercise ( <i>n</i> = 12) |
|--------------------|--------------------------|---------------------------|
| Age                | 55.2 $\pm$ 8.4           | 61.75 $\pm$ 9.6           |
| Stage I            | 2                        | 4                         |
| Stage II           | 6                        | 7                         |
| Stage III          | 2                        | 1                         |
| ER+                | 7                        | 9                         |
| ER-                | 3                        | 3                         |
| Type of treatment* |                          |                           |
| Surgery            |                          |                           |
| Lumpectomy         | 10                       | 10                        |
| Mastectomy         | 0                        | 2                         |
| Chemotherapy       |                          |                           |
| AC                 | 2                        | 5                         |
| AC+Taxol           | 5                        | 5                         |
| CMF                | 1                        | 0                         |
| AI only            | 1                        | 0                         |
| Radiation          | 9                        | 10                        |
| Taking TAM or AI   | 7                        | 9                         |
| Exercise           |                          |                           |
| Sedentary          | 6                        | 6                         |
| Irregular          | 1                        | 3                         |
| Daily              | 3                        | 3                         |
| PMH*               |                          |                           |
| Unremarkable       | 3                        | 2                         |
| Hypothyroid        | 3                        | 6                         |
| HTN                | 3                        | 3                         |
| DM                 | 1                        | 1                         |
| Hyperlipidemia     | 3                        | 3                         |
| Osteoarthritis     | 3                        | 2                         |
| SLE                | 1                        | 0                         |
| COPD               | 0                        | 1                         |
| Asthma             | 0                        | 0                         |

\* Numbers may be greater or less than *n* due to combination therapy and diseases.

**Table 2. Physiological Measures (mean  $\pm$  SD)**

| Dependent Variables  | Pre-treatment     | Post-treatment    | % Change Pre to Post Treatment | <i>P</i> Values<br>t AB *RM |
|--|-------------------|-------------------|--------------------------------|-----------------------------|
| Aerobic capacity (mL.kg <sup>-1</sup> .min <sup>-1</sup> ) |                   |                   |                                |                             |
| Control  | 16.6 ( $\pm$ 5.1) | 15.7 ( $\pm$ 3.7) | -5.4%                          |                             |
| Exercise   | 16.5 ( $\pm$ 8.0) | 21.7 ( $\pm$ 9.4) | 31.5% *t                       | .0012 .005                  |
| BMI  |                   |                   |                                |                             |
| Control  | 30.0 ( $\pm$ 5.7) | 30.0 ( $\pm$ 5.7) | 0%                             |                             |
| Exercise   | 26.5 ( $\pm$ 4.1) | 26.8 ( $\pm$ 4.1) | 1.1%                           | .19 .06                     |
| Body fat %   |                   |                   |                                |                             |
| Control  | 33.3 ( $\pm$ 5.3) | 31.7 ( $\pm$ 5.1) | 4.8%                           |                             |
| Exercise   | 29.7 ( $\pm$ 3.7) | 28.3 ( $\pm$ 3.8) | 4.7% t                         | .61 .0001                   |
| Sit and reach(cm)  |                   |                   |                                |                             |
| Control  | 28.5 ( $\pm$ 9.6) | 30.6 ( $\pm$ 7.3) | 7.3%                           |                             |
| Exercise   | 30.9 ( $\pm$ 7.2) | 33.9 ( $\pm$ 4.8) | 9.7% t                         | .60 .004                    |

\* Significant within (RM) group difference over time,  $P < 0.05$ .

t Significant between (AB) group difference,  $P < 0.05$ .

**Table 3. Psychological Measures (mean  $\pm$  SD)**

| Dependent Variables | Pre-treatment        | Post-treatment       | % Change Pre to Post Treatment | <i>P</i> Values<br>t AB - *RM |
|---------------------|----------------------|----------------------|--------------------------------|-------------------------------|
| SCFS                |                      |                      |                                |                               |
| Control             | 11.8 ( $\pm$ 1.5 SE) | 15.5 ( $\pm$ 2.6 SE) |                                |                               |
| Exercise            | 17.0 ( $\pm$ 1.7 SE) | 8.08 ( $\pm$ .96 SE) |                                | .0003 .01                     |
| LASA                |                      |                      |                                |                               |
| Fatigue             |                      |                      |                                |                               |
| Control             | 31.3 ( $\pm$ 15.8)   | 31.3 ( $\pm$ 34.6)   | 0%                             |                               |
| Exercise            | 41.0 ( $\pm$ 22.9)   | 19.4 ( $\pm$ 29.8)   | 52.6%                          | .10 .17                       |
| Depression          |                      |                      |                                |                               |
| Control             | 7.6 ( $\pm$ 8.0)     | 13.2 ( $\pm$ 19.5)   | -73%                           |                               |
| Exercise            | 23. ( $\pm$ 18.9)    | 2.5 ( $\pm$ 4.01)    | 89% t                          | .005 .0517                    |
| Anxiety             |                      |                      |                                |                               |
| Control             | 16.3 ( $\pm$ 19.7)   | 15.9 ( $\pm$ 21.6)   | 2.4%                           |                               |
| Exercise            | 31.5 ( $\pm$ 26.2)   | 4.2 ( $\pm$ 5.6)     | 86% *t                         | .03 .01                       |
| Confusion           |                      |                      |                                |                               |
| Control             | 6.7 ( $\pm$ 6.5)     | 10.7 ( $\pm$ 19.7)   | -59%                           |                               |
| Exercise            | 21. ( $\pm$ 17.9)    | 6.3 ( $\pm$ 14.1)    | 70% t                          | .04 .1                        |
| Anger               |                      |                      |                                |                               |
| Control             | 4.5 ( $\pm$ 4.6)     | 13.8 ( $\pm$ 23.3)   | 71%                            |                               |
| Exercise            | 14.3 ( $\pm$ 21.4)   | 4.0 ( $\pm$ 8.8)     | 72% t                          | .02 .7                        |
| Energy              |                      |                      |                                |                               |
| Control             | 37.5 ( $\pm$ 23.0)   | 34.7 ( $\pm$ 24.6)   | 7.4%                           |                               |
| Exercise            | 52.6 ( $\pm$ 22.9)   | 31.3 ( $\pm$ 35.7)   | 40.4%                          | .19 .07                       |

\* Significant within (RM) group difference over time,  $P < 0.05$ .

t Significant between (AB) group difference,  $P < 0.05$ .

\*

Figure 1. Peak Aerobic Capacity

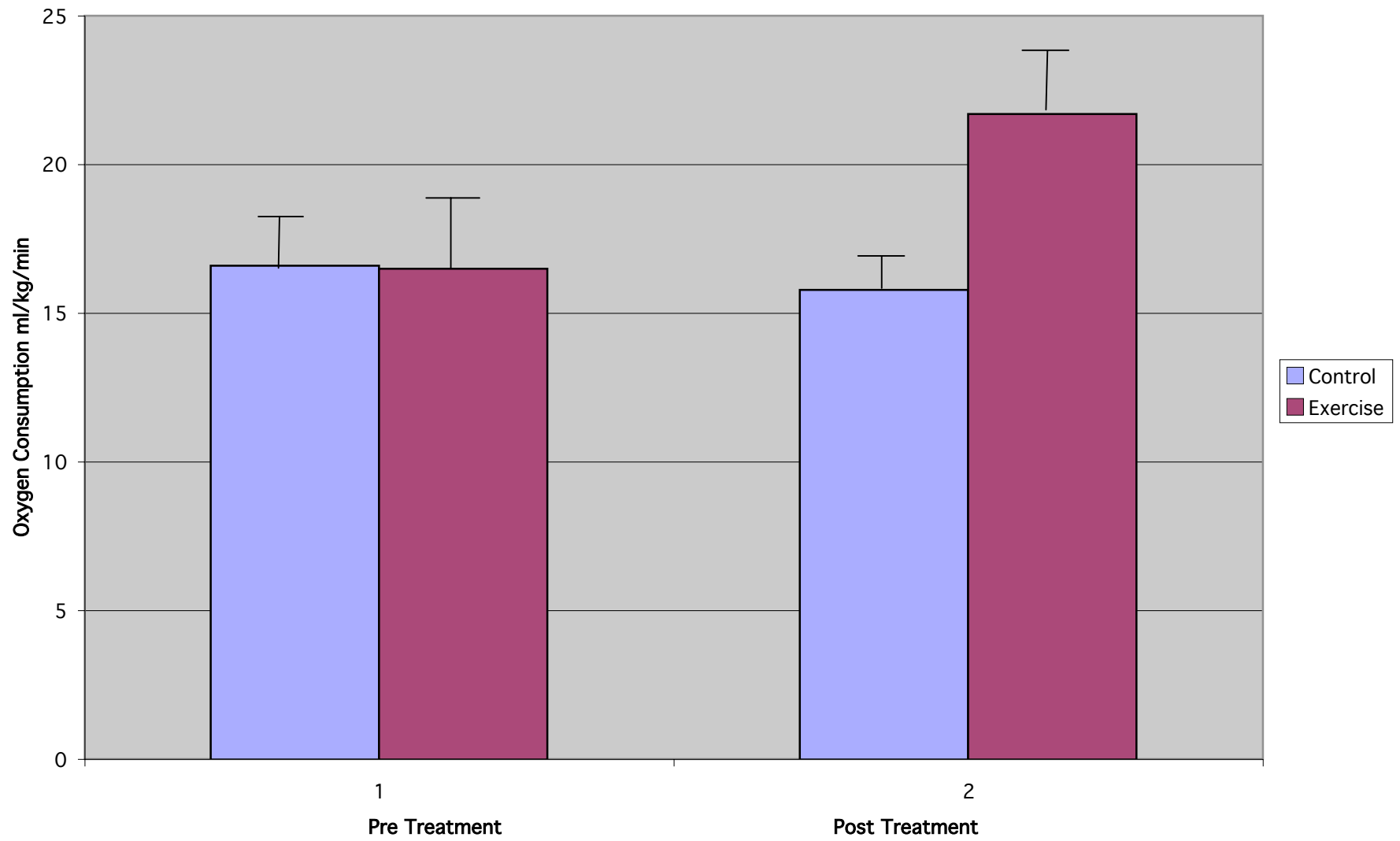




Figure 2. Schwartz Cancer Fatigue Scale

